Remarks

The various parts of the Office Action (and other matters, if any) are discussed below under appropriate headings.

Claim Rejections - 35 USC § 101

Claims 1-17 were rejected under 35 U.S.C. § 101 because the claimed invention was directed to non-statutory subject matter. Claim 1 has been amended to more clearly identify the claimed invention, thereby rendering moot the rejection. Accordingly, the rejection should be withdrawn.

Claim Rejections - 35 USC § 112, 1st ¶

Page 5 of the Office Action states that claims 1-17 are rejected under 35 U.S.C. § 112, 1st paragraph as failing to comply with the enablement requirement. While pages 5-9 set forth the standard for determining whether an enablement rejection is warranted, the Office Action is completely lacking any application of the aforementioned standard to any of the pending claims. Accordingly, the rejection should be withdrawn because the Examiner has failed to "provide a reasonable explanation as to why the scope of protection provided by a claim is not adequately enabled by the disclosure." See MPEP 2164.04.

Further, the amendment to independent claim 1 renders the rejection moot. For at least these reasons, the rejection should be withdrawn.

Claim Rejections - 35 USC § 102 and § 103

Claim 1, as amended, recites a method for identifying advantageous and non-advantageous infusion regions in a tissue that includes, *inter alia*, capturing via an imaging system functional anatomical data and/or structural anatomical data before infusion of a fluid into the tissue, evaluating the captured functional and/or structural anatomical data with computer assistance, and based on the evaluating step, identifying directional channels within the tissue and determining infusion distribution information related to the identified directional channels.

The claimed invention facilitates the identification of advantageous and/or non-advantageous infusion regions based on a capture and evaluation of functional and/or structural before infusion of a fluid into the tissue. The functional and/or structural anatomical data is evaluated to identify directional channels and/or associated infusion distribution information before any infusion fluid is introduced into the patient.

In contrast, Kucharczyk '316 is not understood to disclose or fairly suggest capturing functional and/or structural anatomical data before infusion of a fluid into the tissue. Further, Kucharczyk '316 is not understood to disclose or fairly suggest identifying directional channels and related infusion distribution information based on evaluation of anatomical data that is captured before any infusion fluid is introduced into the tissue.

As understood, Kucharczyk is concerned with tracking the location of delivered materials – i.e., imaging and tracking fluids *after they are infused* into a patient.[1] By infusing the fluid, and then tracking and/or imaging the already-infused fluid, Kucharczyk '316 cannot reasonably be interpreted to disclose the method recited in amended claim 1.

Neither Gillies et al. nor Strommer et al. cure the deficiencies of Kucharczyk '316. For at least these reasons, the rejection of claim 1 and claims 2-16 should be withdrawn.

Claim 18, as amended, recites a device for assisting planning for introducing an infusion fluid into regions of the brain that includes, *inter alia*, an imaging device that captures functional and/or structural anatomical data before an infusion of fluid into regions of the brain, and a processor that performs and assists in evaluating the functional and/or structural anatomical data in order to identify directional channels within the regions of the brain and determine infusion distribution information related to the identified directional channels, where the directional channels and infusion distribution information are indicative of advantageous and non-advantageous infusion regions.

The claimed processor also produces and evaluates a distribution simulation before the infusion fluid is infused, the distribution simulation being indicative of an infusion fluid when it is introduced at particular points, on the basis of the captured anatomical data.

For at least the reasons set forth above with respect to claim 1, claim 18 and claims 19-20 dependent therefrom distinguish patentably over Kucharczyk '316, taken alone or in combination with Gillies et al. and Strommer et al.

In addition, Kucharczyk '316, taken alone or in combination with Gilles et al. and/or Strommer et al. fails to disclose or fairly suggest a processor that produces and evaluates a distribution simulation before the infusion fluid is infused, where the

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[1] Kucharczyk '316 is replete with passages consistent with this understanding. See, e.g., col. 7, ln 8-10, col. 7, ln. 45-55, col. 8, ln. 12-15, col. 8, ln. 57-61, col. 11, ln. 13-18.

distribution simulation being indicative of an infusion fluid when it is introduced at particular points, on the basis of the captured anatomical data.

For at least these additional reasons, the rejection should be withdrawn.

Conclusion

In view of the foregoing, request is made for timely issuance of a notice of allowance.

Respectfully submitted,

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